



MEMORANDUM

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

THROUGH: Vincent Tolino /S/ 11/7/06
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 10/27/06
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: Conflict of Interest Waiver for Clyde W. Yancy, M.D.

I am writing to request a waiver for Clyde W. Yancy, M.D., a member of the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Yancy a waiver under section 208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee or his employer has a financial interest. Since Dr. Yancy is a special Government employee, this individual is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him or his employer.

Dr. Yancy has been asked to participate in the Panel's discussion of issues related to stent thrombosis in coronary drug-eluting stents (DES). These stents contain drugs that potentially reduce the chance the arteries will become blocked again. The discussion will also include issues regarding the association between DES thrombosis and the [-----].
Thirty-three firms are currently identified as manufacturers of stent, drug or delivery components, and 18 firms produce devices that are alternative technologies to drug-eluting stents. These matters are coming before the Circulatory System Devices Panel for consideration and are particular matters of general applicability.

Dr. Yancy has advised the FDA that he has financial interests which could potentially be affected by his participation in this matter. Dr. Yancy serves as [-----] of a Steering Committee for a

[-----], sponsored by [-----], a stent manufacturer as well as a manufacturer of alternative technologies. Known as [-----]. He receives less than [-----]year for this ongoing arrangement, which is unrelated to the matters before the Panel. He also serves on a speaker's bureau for [-----], a manufacturer of an agent under investigation for use on DES. As part of the agreement,[-----]. Total amount expected is less than [----].

The functions of the committee, as stated in its Charter, are to review and evaluate available data concerning the safety and effectiveness of marketed and investigational devices and advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; review classification as appropriate; recommend exemption to certain devices from the application of portions of the Act; advise on the necessity to ban a device; and respond to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. As a member of the Circulatory System Devices Panel, Dr. Yancy potentially could become involved in matters that affect [-----] and [-----] and its subsidiaries. Under section 208, Dr. Yancy is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting this individual to participate in such matters, as you deem appropriate.

For the following reasons, I believe it would be appropriate for you to grant a waiver to Dr. Yancy allowing him to participate in matters identified below.

First, the issues to be addressed by the Panel are particular matters of general applicability, involving an entire class of products and granting no advantage to any individual manufacturer. Therefore, the Panel recommendations would not be expected to have a significant financial impact on any specific firm and the potential perception of bias on the part of the SGE should be mitigated.

Second, given the nature of Dr. Yancy's unrelated consulting arrangements with [-----] and [-----] it is unlikely that recommendations of the Panel will impact the viability of these large firms or his ongoing relationships with them. Therefore, potential concern that Dr. Yancy's impartiality might be called into question during Panel deliberations should be diminished.

Third, the Panel's role is advisory in nature and the Agency officials making the decisions are not bound by the recommendations of the Panel. Therefore, the Agency will take into consideration the SGE's interests when making a final decision.

Lastly, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. Also, the committee's intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interest and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Yancy is Professor of Medicine and Cardiology and the Medical Director of Heart Failure/Transplantation at the University of Texas Southwestern Medical Center in Dallas. A seasoned veteran on the Panel, he brings to the Panel a surgical perspective and his cardiology experiences. His tremendous knowledge of cardiovascular surgical techniques along with a clinical affairs background makes him a well-rounded participant in this discussion of drug-eluting stents. Dr. Yancy will be able to thoughtfully address any surgical complications that result from DES complications. As a non-invasive cardiologist, he brings necessary balance to the Panel, given a significant participation by interventional cardiologists and cardiac surgeons. He will also be able to speak to the needs and concerns of patients. The Agency recognizes that there has been significant media coverage of the issues of stent thrombosis and antiplatelet therapy and its discussion in the clinical community; having seen and heard this coverage, patients are approaching their doctors for guidance. Dr. Yancy's experience in working with patients outside the setting of a pending intervention will be crucial to a successful discussion of these issues. The Center's efforts to obtain other SGEs with such expertise and availability on the specified meeting dates have not been successful.

Accordingly, I recommend that you grant Dr. Yancy a waiver allowing him to participate fully in all official matters before the Panel regarding issues related to stent thrombosis in coronary drug-eluting stents. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Yancy outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE:	<u>/S/</u>	<u>11/7/06</u>
	Vincent Tolino	Date
	Director, Ethics and Integrity Staff	
	Office of Management Programs	
	Office of Management	

DECISION:

 X Waiver granted based on my determination made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for conflict of interest created by the financial interest attributable to the individual.

 Waiver denied.

<u>/S/</u>	<u>11/16/06</u>
Randall Lutter, Ph.D.	Date
Associate Commissioner for Policy and Planning	